MAR 17 2000

K000087

Section H – 510(K) Summary

Date Summary Was Prepared: January 11, 2000

Submitter's Information:
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Contact:
Regina Yeh
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The Kendall Company
Telephone: 508-261-8404
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Device Trade Name: Mahurkar® Triple Lumen Catheter

Device Common Name: Catheter, Intravascular, Short-Term

Classification Panel: General Hospital

Legally Marketed Devices To Which Substantial Equivalence Is Claimed To: The Mahurkar® Triple Lumen Catheter is substantially equivalent to MedComp Tri-Flow™ Soft Tip Triple Lumen Catheter, and Mahurkar® Dual Lumen Catheter.

Device Description: The Mahurkar® Triple Lumen Catheter features three lumens. The catheter has a 12 Fr radiopaque polyurethane catheter shaft with two large lumens (proximal and distal) and one smaller medial lumen running longitudinally along the length of the catheter shaft. The lumina can be distinguished by the color-coded luer-lock adapters on the clear silicone rubber extensions. The two large lumens have curved extensions, and the smaller medial lumen has straight extension tubing. The catheter is available in various implantable lengths.

Mahurkar® Triple Lumen Catheter is available in a "kit" or "tray" configuration which contains the sterile catheter as well as accessory items needed for insertion.

Section H – 510(K) Summary

Intended Use: Mahurkar® Triple Lumen Catheter is intended for short-term central venous access for infusion of IV fluids or drugs, parenteral nutrition, transfusion of blood and blood products, blood sampling and continuous therapies.

Technological Characteristics: The technological characteristics of the Mahurkar® Triple Lumen Catheter, including catheter type, intended use, insertion method, insertion sites, number of lumens and infusion flow rate performance are similar to the MedComp Tri-Flow™ Triple Lumen Catheter. The catheter's design, materials of construction, and mechanical characteristics are similar to the Mahurkar® Dual Lumen Catheter.

Performance Data: Performance data for Mahurkar® Triple Lumen Catheter were compared to that of the predicate devices identified in this 510(K) summary. These test results demonstrate that the device is substantially equivalent to the predicate devices commercially distributed for the same intended use.

Regina S. Yeh
Senior Regulatory Affairs Specialist
The Kendall Company

1/11/2000
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2000

Ms. Regina S. Yeh
Senior Regulatory Affairs Specialist
The Kendall Company
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K000087
Trade Name: Mahurkar® Triple Lumen Catheter
Regulatory Class: II
Product Code: FOZ
Dated: January 11, 2000
Received: January 12, 2000

Dear Ms. Yeh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000087

Appendix 1

Indications for Use Statement

Device Name:

Mahurkar® Triple Lumen Catheter

Indications for Use:

Mahurkar® Triple Lumen Catheter is intended for short-term central venous access for infusion of IV fluids or drugs, parenteral nutrition, transfusion of blood and blood products, blood sampling and continuous therapies.

Please Do Not Write Below This Line – Continue On Another Page If Needed

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000087